REMARKS

1. Formal Matters

a. Status of the Claims

Claims 21-40 are pending in this application. Claims 24-32 and 36-40 are hereby canceled without prejudice to pursuing claims with a similar scope in a continuing application. Claims 21-23 and 33-35 are amended. Upon entry of these amendments, claims 21-23 and 33-35 are pending and under active consideration. Applicants respectfully request entry of the amendments and remarks made herein into the file history of the instant application.

b. Amendments to the Claims

Claim 21 is amended to recite that the isolated nucleic acid consists of X nucleotides, wherein X=18 to 120, which is a rephrasing of the limitation, "An isolated nucleic acid consisting of 18 to 120 nucleotides" of previously presented claim 21. Support for this length limitation can be found at paragraph 0014 of the application as originally filed, which in part recites, "RNA encoded by the bioinformatically detectable novel viral gene is about 18 to about 24 nucleotides in length, and originates from an RNA precursor, which RNA precursor is about 50 to about 120 nucleotides in length." Hence, nucleotides between 18 to 120 nucleotides in length are disclosed.

Claim 21 is also amended to recite that the sequence of the nucleic acid comprises Y consecutive nucleotides of SEQ ID NO: 5264, wherein Y \geq 24, support for which can be found at Table 1, lines 15221-15225 of the application as originally filed. Table 1 discloses SEQ ID NO: 5264, which is 24 nucleotides in length.

Claim 21 is further amended to recite that the sequence of the nucleic acid comprises Z nucleotides of nucleotides 51-69 of SEQ ID NO: 2194, wherein Z=18 or 19, support for which can be found at Table 1, lines 15221-15225 and Table 2, lines 151383-151482. Table 1 discloses GAM2191 (SEQ ID NO: 2194). Table 2 discloses, for example, that a miRNA encoded by GAM2191 is capable of binding the target genes AKAP13 (binding site sequence set forth in SEQ ID NO: 28470) and YWHAZ (binding site sequence set forth in SEQ ID NO: 18201) respectively, as follows:

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GENE	TARGET	UTR	SEQUENCE	SEQID	BINDING-SITE	
======		===			=========	
GAM2191	AKAP13	3'	CAACTAGAGCACTG	28470	AAC	CC
					TAACTAGGG	CACTG
						11111
					GTTGATCTC	GTGAC
						_
G3340101	3717113 67	2.1		10001	7.0	
GAM2191	YWHAZ	3'	CAACTAAGGAGAGATTTGCTGC	18201		CCCA
					TAACTAGGGA	CTGC
						1111
					GTTGATTCCT	GACG
					CT	CTAAAC

As shown above, the first alignment under the designation "Binding Site" of Table 2 is between a miRNA of GAM2191 (nucleotides 51-68 of SEQ ID NO: 2194) and AKAP13. The alignment discloses that GAM2191 is capable of forming a miRNA of 18 nucleotides with the sequence TAACTAGGGAACCCACTG. The second alignment shown above is between a miRNA of GAM2191 (nucleotides 51-69 of SEQ ID NO: 2194) and YWHAZ. This alignment discloses that GAM2191 is capable of forming a miRNA of 19 nucleotides with the sequence TAACTAGGGAACCCACTGC. These sequences correspond to the region of nucleotides 51-69 of SEQ ID NO: 2194 as follows (SEQ ID NO: 5264 is also shown in relation to 51-69 of SEQ ID NO: 2194 miR sequence):

SEQ ID NO: 2194 GTACTGGGTCCCTGGTTAGACCAGATCTGAGCCTGGGAGCTCTCTGGCTAACTAGGGAACCCACTGC
nt 51-69 TAACTAGGGAACCCACTGC
SEQ ID NO: 5264 TCTCTCTGGTTAGACCAGATCTGAGC

Claim 21 is also amended to recite that the nucleic acid comprises a sequence at least 73.7% identical to Z nucleotides of nucleotides 51-68 of SEQ ID NO: 2194, support for which can be found at Table 2, lines 151383-151482 of the application as originally filed. Table 2 shows that GAM2191 (SEQ ID NO: 2194) is capable of forming a miRNA that binds to the target gene YWHAZ (binding site sequence set forth in SEQ ID NO: 18201) with 14 out of 19 bases complementary, as follows:

GENE	TARGET	UTR	SEQUENCE	SEQID	BINDING-SITE	
		===				=======
GAM2191	YWHAZ	3'	CAACTAAGGAGAGATTTGCTGC	18201	ACCCA	
					TAACTAGGGA	CTGC
					GTTGATTCCT	GACG
					CTCTAAAC	

The ratio 14/19, expressed as a percentage rounded up to the nearest tenth, is equivalent to 73.7%.

Claim 22 is amended to recite a nucleic acid of claim 21, wherein X=Y, support for which can be found at SEQ ID NO: 5264 of the application as originally filed. Antecedent basis for X and Y can be found in amended claim 21.

Claim 23 is amended to recite a nucleic acid of claim 21, wherein X=Z, support for which can be found as described above for claim 21. Antecedent basis for X and Z can be found in amended claim 21.

Claim 33 is amended to recite that the vector comprises the nucleic acid of claim 21. This is a rephrasing of the limitation of previously-presented claim 33, "A vector comprising an insert, wherein an insert consists of the nucleic acid of claim 21." This amendment was to clarify the claim language and was not done for any reasons of patentability.

Claim 34 is amended to recite a vector comprising the nucleic acid of claim 22, support for which can be found at paragraphs 0023-0026 of the application as originally filed.

Claim 35 is amended to recite a vector comprising the nucleic acid of claim 23, support for which can be found at paragraph 0023-0026 of the application as originally filed.

2. Patentability Remarks

a. 35 U.S.C. § 112, 2nd paragraph

On page 3 of the Office Action, the Examiner rejects claims 21-40 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claim 21

On page 3 of the Office Action, the Examiner asserts that the phrase "at least 56/69" in claim 21 was indefinite. In view of the foregoing amendments, the phrase "at least 56/69" has been deleted without prejudice thereby rendering the rejection moot.

Claims 31 and 32

On page 3 of the Office Action, the Examiner alleges that the phrase "at least 14/21 complementary" is vague and unclear. As discussed above, claims 31 and 32 have been canceled without prejudice thereby rendering the indefiniteness rejection of these claims moot.

Claims 37 and 38

On page 3 of the Office Action, the Examiner asserts that the phrase "a gene expression inhibition system" in claims 37 and 38 is allegedly vague and unclear. Without prejudice to

seeking claims with similar scope in a continuing application, Applicant has canceled claims 37 and 38 thereby rendering the indefiniteness rejection moot.

Claims 39 and 40

On page 3 of the Office Action, the Examiner asserts that the phrase "a gene expression detection system" in claims 39 and 40 is vague and unclear. In view of the foregoing amendments, claims 39 and 40 have been canceled without prejudice thereby rendering the indefiniteness rejection of these claims moot.

Conclusion

In view of the foregoing amendments, Applicant respectfully submits that the rejection of claims 21, 31, 32, 37, 38, 39, 40, and their dependents under 35 U.S.C. § 112, second paragraph, has been rendered moot, and thereby requests that the rejection be reconsidered and subsequently withdrawn.

b. 35 U.S.C. § 112, 1st paragraph

On pages 3-7 of the Office Action, the Examiner rejects claims 29-40 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time that the application was filed, had possession of the claimed invention. The Examiner also asserts that this is a new matter rejection.

New Matter

On page 5 of the Office Action, the Examiner alleges that Tables 1 and 2 could not be located in the instant application and requests that Applicant identify the pages and line numbers where Tables 1 and 2 can be found. Applicant respectfully submits that Tables 1 and 2 were submitted on compact disk with the application on August 27, 2003. Applicant points to the CD Submission Review Results generated by the Office on August 28, 2003 and submitted herewith as Exhibit A.

The first page of Exhibit A indicates that large tables are included on the CD and that there are no problems with the CDs in the submission. Furthermore, page 2 of Exhibit A shows that the CD contains Table 1.txt, which is 1Mb in size, and Table 2.txt, which is 14Mb in size. Applicant submits that these are Tables 1 and 2 of the instant application, respectively. Should

the Examiner be unable to obtain Tables 1 and 2, or the CD containing these Tables, Applicant will resubmit these Tables.

Applicant respectfully submits that claims 29-40 are supported by the subject matter disclosed in Tables 1 and 2 of the application as originally filed. Hence, claims 29-40 do not contain new matter. Accordingly, Applicant respectfully requests that the rejection of claims 29-40 under 35 U.S.C. § 112, first paragraph, for allegedly having new matter be reconsidered and withdrawn.

Claims 21 and 24, "at least 18 to 20"

On page 4 of the Office Action, the Examiner asserts that no support for the phrase "at least 18 to 20" recited in claims 21 and 24 can be found in the specification. In view of the foregoing amendments, Applicant respectfully disagrees.

For purposes of this reply, Applicant will assume the Examiner was objecting to the phrase "at least 18 consecutive nucleotides," which is recited in limitation (a) of claim 21. Applicant respectfully requests clarification if this interpretation is erroneous.

The Applicant respectfully submits that the phrase "at least 18 consecutive nucleotides" has been removed from claim 21 and 24 without prejudice. Accordingly, the Examiner's rejection of claims 21 and 24 regarding the phrase "at least 18 consecutive nucleotides" is moot.

Claims 31 and 32, "at least 14/21 complementary"

On page 4 of the Office Action, the Examiner asserts that no support for the phrase "at least 14/21 complementary" recited in claims 31 and 32 can be found in the specification. Applicant respectfully disagrees because the ratio of 14/21 corresponds to the number of complementary bases between the claimed nucleic acids and a target binding site as described in Table 2, lines 151383-151482. As discussed above, claims 31 and 32 have been canceled without prejudice thereby rendering the rejection moot.

Claim 21, "18-120 nucleotides"

On page 4 of the Office Action, the Examiner asserts that no support for the size limitation of 18 to 120 nucleotides recited in claim 21 can be found in the specification. Applicant respectfully disagrees.

Applicant respectfully submits that, as described above in support of amended claim 21, paragraph 0014 of the application as originally filed, recites in part, "RNA encoded by the bioinformatically detectable novel viral gene is about 18 to about 24 nucleotides in length, and

originates from an RNA precursor, which RNA precursor is about 50 to about 120 nucleotides in length." Hence, nucleotides between 18 to 120 nucleotides in length are disclosed such that one of ordinary skill in the art would be able to conclude that the claimed subject matter is described in the specification. Accordingly, Applicant respectfully requests that the rejection of claim 21 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Claims 21 and 24, "an RNA equivalent"

On pages 4 and 5 of the Office Action, the Examiner asserts that no support for the phrase "an RNA equivalent of (a)" as indicated in claims 21 and 24, can be found in the specification. Applicant respectfully disagrees.

Paragraph 0014 of the specification as filed recites in part "RNA encoded by the bioinformatically detectable novel viral gene." Hence, RNAs encoded by the disclosed viral genes are described in the application as filed, and one of ordinary skill in the art would be able to conclude that the claimed subject matter is described in the specification. Accordingly, Applicant respectfully requests that the rejection of claims 21 and 24 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Claims 21-40

On pages 5-7 of the Office Action, the Examiner rejects claims 21-40 under 35 U.S.C. § 112, first paragraph, for allegedly lacking proper written descriptive support. Specifically, the Examiner asserts that 81% or higher variant sequences to SEQ ID NO: 2194 encompass a large genus of nucleic acids that are not disclosed or are different from the disclosed sequences. The Examiner asserts that the limitation "at least 56/69 identical to (a) or (b)" of claims 21 and 24 has no record or description in the application at the time of filing that would demonstrate to one of ordinary skill in the art that the Applicant was in possession of variants of SEQ ID NOs: 2194 and 5264. Applicant respectfully disagrees.

The ratio of 56/69 corresponds to the number of complementary base pairs within the stem loop structure of the nucleotide sequence as set forth in SEQ ID NO: 2194. Support for the ratio 56/69 can be found at Table 1, lines 15221-15225. Applicant respectfully submits that one of ordinary skill in the art would clearly recognize that this degree of complementarity can be described as a ratio and corresponds to the amount of variance allowed in the VGAM2191 sequence. Nevertheless, in order to expedite prosecution and without prejudice to seeking claims

of similar scope in continuing applications, Applicant has stricken the ratio "56/69" from the claims, thereby rendering the rejection of claims 21 and 24 moot.

In view of the foregoing amendment and remarks, Applicant respectfully requests that the rejection of claims 21-40 under 35 U.S.C. § 112, first paragraph, for allegedly lacking proper written descriptive support, be reconsidered and withdrawn.

c. 35 U.S.C. §§ 101 and 112

At pages 7-13 of the Office Action, the Examiner rejects claims 21-40 under 35 U.S.C. § 101, for allegedly lacking utility. In order to satisfy the utility requirement under the Revised Interim Utility Guidelines, a specific and substantial utility must either (i) be cited in the specification or (ii) be recognized as well as established in the art, and the utility must be credible.

(1) Specific Utility

A specific utility is defined in the Revised Interim Utility Guideline Training Materials ("RIUGTM") as a utility that is specific to the particular claimed subject matter, which is in contrast to a general utility that would be applicable to a broad class of the invention. For example, a claim to a polynucleotide of which use is disclosed simply as a "gene probe" or "chromosome marker" is not considered to be specific in the absence of a disclosure of a specific DNA target. See RIUGTM at page 5.

At page 12 of the Office Action, the Examiner alleges that the specification does not disclose any modulation of any specific gene nor any biological or biochemical function for the claimed polynucleotides. Applicant respectfully disagrees. The specification identifies specific genes of interest for which the claimed polynucleotides may be used to regulate expression.

At paragraphs 30615, 30617, and 30624 of the specification, it is asserted that the disclosed polynucleotides may be used to target and modulate expression of particular host target gene transcripts. Furthermore, paragraphs 30625, 30626, and 30628 of the specification disclose that the claimed polynucleotides, which are related to miRNAs encoded by the VGAM2191 gene, modulate expression by inhibiting translation of particular target mRNA transcripts as shown in Table 2. Table 2 discloses that 20 specific human host genes (*i.e.*, ITGA5, SCD, SF3B3, SLC22A11, SLC4A4, ZNF180, AKAP13, DNAH11, FGFR2, GTF2E2, ILK, KIF3B, MAP1B, MLH3, MYO1A, POMZP3, TRPM2, UTY, YWHAZ, and ZP3A) are targeted by the

claimed miR sequences as set forth in SEQ ID NO: 5264 and nucleotides 51-69 of SEQ ID NO: 2194.

(2) Specific Utility

A substantial utility is defined in the RIUGTM as a utility that defines a "real world" use, which is in contrast to the need to carry out further research to identify or confirm a "real world" context. As discussed above, the claimed polynucleotides may be used to regulate expression of proteins encoded by the human host genes ITGA5, SCD, SF3B3, SLC22A11, SLC4A4, ZNF180, AKAP13, DNAH11, FGFR2, GTF2E2, ILK, KIF3B, MAP1B, MLH3, MYO1A, POMZP3, TRPM2, UTY, YWHAZ, and ZP3A. Igarashi et al., J. Am. Soc. Nephrol. 12:713-718 (2001), which is submitted on the Information Disclosure Statement filed herewith, discloses that the gene SLC4A4 (which encodes a kidney Na⁺, HCO₃⁻ cotransporter) is known to be associated with a disease, type II renal tubular acidosis. Similarly, Han et al., Proc. Nat. Acad. Sci. USA, 94: 4954-9 (1997), which is submitted on the Information Statement filed herewith, discloses that the gene YWHAZ or $14-3-3\zeta$ encodes a protein that is (i) implicated in nitrogenous and oncogenic transformation; and (ii) interacts with RINI, a protein that interacts with activated RAS and is implicated as being involved in tumorigenesis. One of ordinary skill in the art would recognize that the claimed polynucleotides may be used to regulate expression of genes such as SLC4A4 and YWHAZ and thereby elucidate the role of these target genes in their associated diseases. Accordingly, Applicant respectfully submits that the specification provides a substantial utility for the claimed polynucleotides.

(3) Credible Utility

According to the RIUGTM, an asserted utility is credible if the assertion is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided. An assertion is credible unless (i) the logic underlying the assertion is seriously flawed, or (ii) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. See RIUGTM at page 5.

At page 12 of the Office Action, the Examiner asserts that a credible utility is lacking because the claimed polynucleotides are simply research intermediates and no evidence is found suggesting that the claimed polynucleotides have been isolated, cloned, detected, expressed or even analyzed in any living cell *in vitro* or *in vivo*. Applicant respectfully disagrees.

Applicant respectfully submits that the Examiner has not considered the asserted utility as discussed above for using the claimed polynucleotides for modulating expression of specific mRNA targets. Whether or not the claimed polynucleotides actually exist in a biological system, and whether the true biological function of any predicted miRNA sequence has been validated according to Krutzfeldt (cited by Examiner on pages 9 and 10 of the Office Action) are irrelevant. The proper inquiry is instead whether a person of ordinary skill in the art would believe that the claimed polynucleotides <u>may be</u> used to modulate expression of the specific mRNA targets.

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Paragraph 0120 of the application discloses that the mRNA targets of the claimed polynucleotides were identified as being consistent with the free energy and spatial structure of target binding sites of known miRNAs. The method as described in paragraph 0120 for identifying target binding sites of miRs is based upon studies at the time of filing demonstrating that miRs bind to target binding sites as disclosed in references such as Wightman *et al.* (1993), Reinhart *et al.* (2000), Slack *et al.* (2000), Lau *et al.* (2001), Lagos-Quintana *et al.* (2001), and Moss *et al.* (1997), which are all cited in the Information Disclosure Statement filed October 26, 2006 under reference numbers 30, 260, 300, 780, 790, and 100, respectively. In view of the asserted utilities being consistent with the general understanding of miRNAs and their target binding sites at the time of filing, Applicant respectfully submits that one of ordinary skill in the art would believe that each claimed polynucleotide would bind its respective target binding sites.

In view of the foregoing remarks and lack of showing that Applicant's assertion of utility is seriously flawed or logically inconsistent, the Applicant respectfully submits that a credible utility is asserted for the claimed polynucleotides.

d. 35 U.S.C. §112, first paragraph

On page 13 of the Office Action, the Examiner rejects claims 21-40 under 35 U.S.C. §112, first paragraph, for allegedly lacking an enabling disclosure because one of skill in the art would not know how to use the invention because there is not specific and substantial asserted utility, or alternatively, a well established utility. In view of the foregoing remarks to overcome the utility rejection under 35 U.S.C. § 101, Applicant respectfully submits a specific, substantial, and credible utility has been established, thereby enabling one of skill to use the claimed invention. Applicant therefore respectfully submits that the rejection of claims 21-40 under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement be reconsidered and withdrawn.

e. 35 U.S.C. § 102(b)

On pages 13-15, the Examiner rejects claims 21, 23, 24, 26-32, 35, and 36 under 35 U.S.C. § 102(b) for allegedly being anticipated by Temsamani et al (WO 96/23878) ("Temsamani" hereafter). Temsamani allegedly teaches an oligonucleotide of 20 nucleotides with the sequence of CTGGTTAGACCAGATCTGAG (as set forth in SEQ ID NO: 9) that is 83.3% identical to nucleotides 4-23 of SEQ ID NO: 2194 of the instant application. In view of the foregoing amendment, Applicant respectfully disagrees.

Applicant respectfully additionally notes that the sequence SEQ ID NO: 9 of Temsamani may overlap with nucleotides 4-23 of SEQ ID NO: 5264. For purposes of this reply, Applicant will assume this alignment to be correct. Applicant respectfully requests clarification if this interpretation is erroneous.

For the Examiner's convenience, an alignment is presented below between SEQ ID NO: 2194 (hairpin) / SEQ ID NO: 5264 (miR) of the instant application and SEQ ID NO: 9 of Temsamani.

```
SEQ ID NO: 2194 GTACTGGGTCTCTGGTTAGACCAGATCTGAGCCTGGGAGCTCTCTGGCAACCCACTGC
SEQ ID NO: 5264 TCTCTGGTTAGACCAGATCTGAGC
Temsamani (SEQ ID NO:9) CTGGTTAGACCAGATCTGAG
```

As shown above, the sequence alignment between the relevant cited nucleotides of Temsamani, SEQ ID NO: 5264, and nucleotides 51-69 of SEQ ID NO: 2194 indicates that Temsamani's sequence (SEQ ID NO: 9) is only 20 nucleotides in length and does not align with nucleotides 51-59 of SEQ ID NO: 2194. Applicant respectfully submits that limitation (a) of amended claim 21 recites a sequence comprising Y nucleotides of SEQ ID NO: 5264, wherein Y≥24. Accordingly, Temsamani does not teach a nucleic acid of 24 nucleotides in length. In addition, limitation (b) of amended claim 21 is directed to Z nucleotides of nucleotides 51-69 of SEQ ID NO: 2194 wherein Z = 18 or 19. Applicant submits that SEQ ID NO: 9 of Temsamani does not overlap with nucleotides 51-69 of SEQ ID NO: 2194. Accordingly, Temsamani does not teach a nucleic acid that is at least 24 nucleotides of SEQ ID NO: 5264, nucleotides 51-69 of SEQ ID NO: 2194 or at least 73.7% variants thereof, or complements thereof.

Similarly, amended claim 23 is not directed to a nucleic acid of 20 nucleotides in length comprising the sequence of SEQ ID NO: 5264, but instead is directed to a nucleic acid comprising nucleotides 51-69 of SEQ ID NO: 2194. As discussed above, claims 24, 26-32, and 36 are canceled without prejudice. Accordingly, in view of the foregoing amendments and

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remarks, Applicant respectfully requests that the rejection of claims 21, 23, 24, 26-32, 35, and 36 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

POLSINELLI SHALTON FLANIGAN SUELTHAUS PC

Dated: May 8, 2007 By: /Paul Jenny/

Paul Jenny

Registration No.: 59,014 Customer No.: 37808

POLSINELLI SHALTON FLANIGAN SUELTHAUS PC 180 N. Stetson Ave., Suite 4525 Chicago, IL 60601 312.819.1900 (main) 312.873.3620 (direct) 312.602.3955 (efax)

pjenny@polsinelli.com

Exhibit A

Internal Worksheet Only - Do Not Scan

CD Submission Review Results

Application Number	10/604945	Receipt Date	8-28-03			
	700113		8-58-03			
New Application	Response to Notice	Date of Response				
Jumbo – Large ta	ables are included on the CD					
There are no pro	There are no problems with the CDs in the submission.					
Items checked below are to be selected in the PALM Pre-Exam CD problem list.						
Omitted Items						
Files on compact	disc are unreadable:					
Disc(s) of either se	et not readable:					
	tain file names listed:					
	sing unamended files:					
Missing compact o	liscs:					
Missing Parts						
Disc(s) do not contain file names listed:						
Discs contains files that are non-ASCII files:						
Only one copy of the CD, no duplicate:						
	Wrong media type, e.g., CD-RW:					
The transmittal letter and specification do not list information:						
One disc(s) contain	Both disc(s) contain unreadable files:					
Compact disc(s) contain	One disc(s) contain unreadable files: Compact disc(s) contain viruses, but are still readable:					
EFS/Paper Submis	sion.	idable:				
EFS/Paper Submission:						
Table does not maintain data in proper alignment: Not proper subject matter for CD's:						
Informality – If no proble	m, do not send notice, leave l	etter for Examine	r			
No statement in transmittal letter that CD's are the same:						
No incorporation by reference statement for the CD's:						
CD's not labeled "Copy 1" and "Copy 2":						
Deficient CD packaging:						
Deficient Labeling on CD's:						
The transmittal letter does not list information:						
The specification does not list information:						
Table less than 51 p	pages submitted on CD:					
File Directory Attachment						
Conv of file director	e linking in attaches to the					
Conv of file directory	Copy of file directory listing is attached and should be mailed to applicant					
Copy of file directors	Copy of file directory listing is not attached					
Copy of file directory listing is not attached because it is over one page long						

Exhibit A (p. 2)

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File Name	Size
Table1.txt	1Mb
Table2.txt	14Mb